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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Appellant(s): Yang, et al.

Examiner: Chan, Sing P.

Application: 10/074,272

Group Art Unit: 1734

Filed: February 14, 2002

Docket: 1199-4 RCE

Confirmation No: 4926

Date: February 12, 2007

For: THIN FILM WITH NON-SELF-
AGGREGATING UNIFORM
HETERO-GENEITY AND DRUG
DELIVERY SYSTEMS MADE
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REPLY BRIEF

Sir:

Pursuant to 37 C.F.R. §41.41, Appellants file this Reply Brief in response to the Examiner's Answer of December 12, 2006. Appellants address particular points raised by the Examiner and continue to rely on its arguments in the main Appeal Brief.

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A. Status of the Claims

Claims 54, 55, 62-78, 80, 81, 83-91, 93-104, 106, 108-112, 114, 116, 117 and 119 are in the application.

Claims 91, 93-104, 106, 108-112, 114, 116, 117 and 119 are finally rejected and on appeal.

Claims 54, 55, 62-78, 80, 81 and 83-90 are presently withdrawn and not on appeal.

No claims presently stand allowed.

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B. Grounds of Rejection to be Reviewed on Appeal

The following grounds of rejection are to be reviewed on this Appeal:¹

1. Claims 91, 93, 97, 100, 101, 106, 108, 109, 111, 112, 114, 117 and 119 have been rejected under 35 U.S.C. §103(a) as being obvious over U.S. Patent No. 6,660,292 to Zerbe et al. (hereinafter "Zerbe") in view of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter "Strobush") and U.S. Patent No. 5,044,761 to Yuhki et al. (hereinafter "Yuhki").
2. Claims 94 and 95 have been rejected under 35 U.S.C. §103(a) as being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,629,003 to Horstmann et al. (hereinafter "Horstmann").
3. Claim 96 has been rejected under 35 U.S.C. §103(a) as being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 4,478,658 to Wittwer (hereinafter "Wittwer").
4. Claims 98, 99, 102 and 103 have been rejected under 35 U.S.C. §103(a) as being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 6,231,957 to Zerbe et al. (hereinafter "Zerbe '957").
5. Claims 104 and 110 have been rejected under 35 U.S.C. §103(a) as being obvious over Zerbe in view of Strobush, Yuhki and Horstmann.
6. Claim 116 has been rejected under 35 U.S.C. §103(a) as being obvious over Zerbe in view of Strobush, Yuhki and U.S. Patent No. 5,733,575 to Mehra et al. (hereinafter "Mehra").

¹ In addition to the grounds of rejection delineated in this section, the final Office Action dated January 20, 2006 also included an obviousness-type double patenting rejection of claim 119 over claim 1 of Appellants' co-pending Application No. 10/768,809 in view of U.S. Patent No. 5,044,761 to Yuhki et al. As this is a provisional obviousness-type double patenting rejection, it is not being addressed on appeal.

C. Response to Argument

At the outset, the honorable Board is cautioned to carefully review the portions of U.S. Patent No. 5,881,476 to Strobush et al. (hereinafter "Strobush") cited by the Examiner in his Answer. The Examiner tends to misquote, misinterpret and/or take out of context the teachings of Strobush. In other words, the specific column and line of Strobush referred to by the Examiner may not and often **does not** state that which is recited or paraphrased by the Examiner. For example, at page 6 of the Examiner's Answer, the Examiner advises that Strobush teaches that "no gas is supplied when top-side gas is not needed or desired". The Examiner then directs the Board's attention to Col. 11, lines 15-27 of Strobush. The Examiner, however, fails to advise the Board that Strobush specifically explained that top-side gas was not needed or desired "when the drying apparatus 10 is filled with **inert** gas." (Strobush; Col. 11, lines 26-27). It is respectfully submitted that anyone skilled in the art reading Strobush would recognize that the purpose of the inert gas was to preclude explosion of the highly volatile and flammable, organic solvent used by Strobush. On this point, the Board's attention is directed to Col. 4, lines 9-13 of Strobush, which refer to a prior art process that uses an oven filled with inert gas to dry a moving web coated with a coating composition containing a flammable organic solvent.

In the following sections, Appellants will address several specific inconsistencies and inaccuracies found in the Examiner's Answer. In particular, the first section addresses several points in the arguments relating to nonanalogous art. The second section addresses several points in the arguments relating to the suggestion or motivation to combine the cited references.

1. The Examiner's Nonanalogous Art Analysis is Erroneous

At page 16 of the Examiner's Answer, the Examiner correctly sets forth the law on analogous art. In particular, the Examiner states that:

...it has been held that a prior art reference must either be in the field of appellant's endeavor or, if not, then be reasonably pertinent

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to the particular problem with which the appellant was concerned, in order to be relied upon as a basis for rejection of the claimed invention.

(Examiner's Answer, at page 16) (citing *In re Oetiker*, 977 F.2d 1443, 24 U.S.P.Q.2d 1443 (Fed. Cir. 1992)).

The Examiner apparently acknowledges, and it is abundantly clear, that Strobush is not in the field of Appellants' endeavor (e.g. ingestible film dosages). The Examiner, however, asserts that "Strobush is reasonably pertinent to the particular problem with which the appellant was concerned." (Examiner's Answer, at page 16). The Examiner then defines this "particular problem" as "to dry a film coating by applying hot dry gas to the bottom of a coated substrate". (Examiner's Answer, at pages 16-17). This definition of the problem is erroneous. The Examiner's definition of the problem is in fact a method step that forms a part of Appellants' **solution** to the particular problem with which they were concerned.

As explained in Appellants' Appeal Brief, the **problem** with which the inventors were particularly concerned was **forming ingestible films for use as pharmaceutical dosage delivery systems in which each dosage unit, e.g., each individual dosage film unit, contains the proper amount of active**. (Appeal Brief, at page 11). Ensuring the proper amount of active in each ingestible dosage unit is necessary for satisfying federal regulatory requirements for making a commercial product. As further explained in the Appeal Brief and in Appellants' application, the prior art had been unsuccessful in teaching the manufacture of uniform content active-containing film dosage units. (Appeal Brief, at page 11; Application, at page 2, ¶4). Appellants' claimed process provides a **solution** to this problem. Accordingly, the Examiner's statement of the problem as "to dry a film coating by applying hot dry gas to the bottom of a coated substrate" is simply not relevant to the analysis on nonanalogous art.

Then, at page 17 of the Examiner's Answer, the Examiner states that:

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...appellant's argument of 'overcoming the problems of forming edible film strips for individual dosing of actives, particularly drugs, which are safe and effective for human consumption' is not commensurate in scope with the claims. The claims do not require the use of drugs.

Appellants also disagree with this assertion. All of the claims on appeal require the presence of an active in the film composition. **The term "active" is defined in the specification to include a broad list of ingestibles such as pharmaceuticals, medicaments, vitamins and cosmetic actives. All of these actives are for individual dosing and must be safe and effective for human consumption.** Moreover, claims 104 and 110 specifically include pharmaceutical actives, which are commonly referred to as drugs. As such, Appellants' argument is commensurate in scope with all of the claims on appeal, and especially claims 104 and 110. The Examiner's assertion regarding the scope of the claims is erroneous.

Despite the Examiner's first erroneous definition of the problem, he then asserts another, different definition of the problem with which Appellants' allegedly were concerned on page 17 of the Examiner's Answer. In particular, the Examiner states:

In response to appellants argument that appellants are solving a different problem, the examiner combine Strobush method with Zerbe et al with a different reason and therefore for solving a different **problem such as reducing or eliminate coating defect such as mottle or orange peel.**

(Examiner's Answer, at page 17) (emphasis added).

Not only is this definition of the problem inconsistent with the Examiner's previous definition, discussed above, but it is simply **not** the correct analysis. A non-analogous art analysis must first begin with an identification of Appellants' problem. Then, the analysis must focus on whether or not the cited reference is reasonably pertinent to that particular problem. As discussed above, the Examiner incorrectly identified Appellants' problem. Now, the Examiner

fails to even start with his incorrectly identified problem and instead creates his own independent problem based on the cited prior art, i.e., Strobush . The Examiner has substituted Strobush's problem for Appellants' problem, which is not only contrary to the law but also to Appellants' own disclosure of its problem. Nowhere have Appellants stated that the problem they faced was reducing or eliminating coating defects such as mottle or orange peel. Indeed, such coating defects are irrelevant to Appellants' invention. Rather, Appellants' problem, which was to develop safe and effective ingestible uniform content active-containing film dosage units, is described in detail in the Appellants' original application, Appeal Brief and above. The Examiner's response in the passage quoted above, therefore, is inapplicable.

Moreover, it appears from the quoted passage that the Examiner has introduced his reasoning on the motivation to combine references into his analysis on nonanalogous art. Obviousness, particularly motivation to combine, reasoning, however, is not relevant to this inquiry. Appellants' position is that a single reference, Strobush, is nonanalogous art. Because Strobush is nonanalogous art, it cannot properly be combined with **any other references** to reject the claims. Accordingly, the motivation to combine references has absolutely no bearing on this issue.

Furthermore, the Examiner asserts that **he does not** define "mottle" as "uniform thickness or uniform density". (Examiner's Answer, at page 15). Yet, in response to Appellants' argument that "mottle" is a different problem from that solved by the present invention, the Examiner takes the contradictory position that "no mottle defects results in uniform thickness and uniform density". (Examiner's Answer, at page 16). Thus, on the one hand the Examiner states that he does not equate mottle with uniformity of thickness and density, yet when it suits his purpose, he does equate these terms. Then the Examiner takes an even more untenable stance by substituting his own unsupported opinion for that of an expert. For example, the Examiner asserts that he "interprets the non-uniform density as non-uniform distribution of components". (Examiner's Answer, at page 16). This is clearly erroneous. Not only does the

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Examiner fail to provide support for these assertions, these unsupported contentions run directly contrary to those of the declarant, Dr. Rhyta Rounds, as described in detail in the Declaration Under 37 C.F.R. §1.132 by Dr. Rhyta Rounds submitted with Appellants' Response dated May 9, 2006, a copy of which was submitted as Appendix 1 with Appellants' Appeal Brief (hereinafter the "Rounds Declaration"). It is apparent that the Examiner has given no weight to the technical support and opinions set forth in the Rounds Declaration. The Rounds Declaration, however, provides a thorough technical analysis and comparison of the systems of Appellants' invention and Strobush, with technical support. Such declaration by an expert should be given due consideration. *See* MPEP §716.01.

Although the Examiner correctly recognizes that Strobush defines "mottle" as "an undesirable defect because it detracts from the appearance of the finished product" (e.g. a photographic coating), he contends that this is not a surface defect. Appearance by definition is the way something looks, and thus, commonly understood to be a visual defect seen on the surface. Contrary to the Examiner's assertions, mottle is typically understood to be a surface defect experienced in printed images. *See, e.g.*, U.S. GOVERNMENT PRINTING OFFICE, (PUBLICATION GRADE) GLOSS COATED BOOK, JCP A175, FSC 9310 (1999) (specifying that the "Coating and **surface**" should be "free from mottle") (emphasis added); U.S. GOVERNMENT PRINTING OFFICE, MASKING, PHOTOLITHOGRAPHIC (COATED), JCP O-50, FSC 3610 (1999); ROY ROSENBERGER ET AL., BACK-TRAP AND HALF-TONE MOTTLE MEASUREMENT WITH STOCHASTIC FREQUENCY DISTRIBUTION ANALYSIS 1 (2001) (explaining that "Mottle is the non-uniform reflection from a **surface** or transmission of light through a translucent specimen. When the human eye inspects a mottled **surface** it recognizes changes in the luminance from one area to another.") (emphasis added); ROY R. ROSENBERGER, MOTTLE MEASUREMENT OF WET TRAP, BACK TRAP AND OTHER MOTLEY IMAGES 1 (2002) (describing a method of measuring "visually apparent mottle in digital images of printed matter") (copies of each of these references are attached hereto as Exhibit A).

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The Examiner's contentions again run contrary to those described in the Rounds Declaration and again the Examiner has substituted his unsupported opinions for those of an expert. As provided therein, **mottle** as described in Strobush is a **defect in the surface** appearance of the coating. (Appeal Brief App. 1; Rounds Declaration, ¶¶ 10-11, 17). Surface appearance is particularly relevant in Strobush because the reference is mainly directed to forming photographic-type coatings, in which visual appearance on the surface of the image is of utmost concern and necessary for its function, i.e., to produce an acceptable visible image. **Visual appearance**, however, is **distinctly different from compositional uniformity** throughout the body of a film and not relevant to the problem with which Appellants were concerned.

Accordingly, the Examiner's reliance on Strobush's teaching that it "reduces or eliminates one or more coating defects such as mottle and orange peel" is irrelevant. (Examiner's Answer, at page 16). Appellants' invention is not concerned with eliminating mottle or orange peel. Appellants are concerned with uniform distribution and uniformity of content of components and achieves the uniform distribution and content through a method completely different from that described by Strobush.

Moreover, contrary to the Examiner's statement, which equates mottle and orange peel as drying problems, Strobush actually distinguished between Benard cells, orange peel and mottle. Benard cells and orange peel were said to be related problems, but mottle was described as a problem different from Benard cells and orange peel. (Strobush; Col. 1, line 43 to Col. 2, line 5). For example, the Background of Strobush refers to Benard cells and orange peel as defects, stating:

Bernard cells are defects arising from circulatory motion within the coating after it has been applied Orange peel is related to Benard cells. Orange peel is most common in fluid coatings which have a high viscosity to solids ratio. This is due to the tendency of

such systems to “freeze in” the topography associated with Benard cells upon loss of relatively small amounts of solvent.

(Strobush; Col. 1, lines 46-55) (citations omitted).

Appellants’ process does not consider Benard cells as a problem but, rather, encourages and uses the formation of Benard cells to mix the coating during the drying process to ensure uniform distribution in the film. Appellants’ claimed rapid heating of the aqueous coating system, for instance, by applying hot air currents to the bottom side of the film carrier with substantially no top air flow on the surface of the film, generates Benard cells, which help keep the actives (e.g. drug particles) suspended in the matrix and thereby maintain the uniformity of distribution and content required by the claims. This was explained and discussed at the interview on May 3, 2006 by Dr. Rounds and a video of a typical Bernard cell formation was shown.

Finally, at page 19 of the Examiner’s Answer, the Examiner responds to Appellants’ argument that one skilled in the art would not look to Strobush. The Examiner relies on the “Background” portion of Strobush, pointing out that Strobush teaches that “coated substrates are often dried using drying oven with drying gas and bringing the drying gas into contact with the coating”. To begin with, the Examiner has confused a prior art teaching referred to by Strobush with Strobush’s process. Secondly, this prior art teaching is in fact contrary to Appellants’ claims. Appellants agree that the prior art discussed in Strobush does teach that the drying gas should be brought into direct contact with the coating. Appellants’ claims 91 and 117 specifically state that the claimed process is carried out by applying hot air currents to the bottom side of a surface on which the film is carried (e.g. a conveyor belt) and there is substantially no top air flow directly on the film. Appellants’ claim 112 specifically states that the claimed process is carried out by applying hot air to the bottom of the film until a visco-elastic film is achieved. Appellants’ claims 116, 118 and 119 specifically state that the claimed process is

carried out by applying hot air to the bottom to prevent air flow migrations/intermolecular forces from creating aggregates in conglomerates. This is significantly different from “bringing the drying gas into contact with the coating” as recited by the Examiner. Therefore, this argument is inapplicable and contrary to Appellants’ claims.

In sum, the Examiner has inconsistently and inaccurately defined the problem with which Appellants were concerned, substituted his own problem for Appellants’ problem, and consequently, misapplied the nonanalogous art analysis. Appellants have consistently set forth the definition of their problem as developing safe and effective ingestible and uniform content active-containing film dosage units that can be used for oral delivery of actives. Appellants reiterate their arguments from the Appeal Brief that Strobush is **not at all pertinent** to this problem. In reality, it is not reasonable to conclude that Strobush “logically would have commended itself” to Appellants’ attention in considering their particular problem. *See In re Clay*, 966 F.2d 656, 59, 23 U.S.P.Q.2d 1058, 1061 (Fed. Cir. 1992). Simply put, skilled artisans in the field of delivery of actives in oral dosages would never think to consult prior art relating to photographic or thermographic images. Thus, Strobush is **not** analogous art.

2. The Examiner’s Obviousness Arguments are Improper

By twisting the teachings of Strobush, the Examiner forces an erroneous conclusion of obviousness based on a combination of references that includes a primary reference, Zerbe, directed to the preparation of an edible film from an **aqueous** composition and a secondary reference, Strobush, that describes a process designed for an organic solvent system that is directed to solving a completely different problem (**mottle**), which is peculiarly specific to **organic solvent-based** coatings. These references are directed to distinctly different systems. Zerbe provides only the most general of teaching with respect to drying his aqueous system. It is entirely unclear how the Examiner justifies any motivation or suggestion to combine Zerbe with Strobush, whose teachings are so disparate.

a. The Examiner's alleged suggestion or motivation to combine the cited references is improper

At the outset, the Examiner states that directing hot air to the bottom of the substrate and having substantially no top airflow "is well-known and conventional". (Examiner's Answer, at page 6). This statement indicates the Examiner improperly has focused solely on a particular method step and not on the "invention as a whole", which includes the **materials** required to perform the claimed **multi-step** method. Importantly, the Examiner has not provided any references to show that the method step that the Examiner considers to be "well-known and conventional" has been used or suggested for use when aqueous polymeric solutions are applied to a substrate at sufficient thickness to form a "self-supporting edible film", as claimed in Appellants' claim 91. Rather, the Examiner has made only generalized assumptions about the teachings of the prior art and of what skilled artisans would have been "well aware." Such assumptions are insufficient to establish a motivation to combine the cited references. *See, e.g., In re Bruce Beasley*, 117 Fed. Appx. 739, 744 (Fed. Cir. 2004) (unpublished) (stating that "[t]he statements made by the Examiner . . . amount to no more than conclusory statements of generalized advantages and convenient assumptions about skilled artisans" and that "such statements and assumptions are inadequate to support a finding of motivation, which is a factual question that cannot be resolved on 'subjective belief and unknown authority'.").

The Examiner states that it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Strobush and U.S. Patent No. 6,660,292 to Zerbe et al. (hereinafter "Zerbe") because Strobush teaches "to dry the coating on a substrate without mottle and at a higher web speeds". (Examiner's Answer, at page 6). The Examiner points to Col. 6, lines 21-27 of Strobush for support. The issue of mottle has already been addressed. At Col. 6, lines 21-25, however, Strobush clearly states that the higher web speed drying is in relation to coating techniques used in the manufacture of "photothermographic, thermographic, and photographic articles", not self-supporting edible films including a mixture of water and a water-soluble polymer. Nothing in the prior art

suggests the combination of the Strobush and Zerbe processes. Indeed, without the use of Appellants' disclosure as a template, the two references are simply not combinable. The Examiner has clearly used hindsight reconstruction in forming this rejection.

Also as support for his combination of these references, the Examiner advises that Strobush "recites the method and apparatus are suitable for a wide variety of coatings" and that the "evaporable liquid vehicle" of Strobush "would include water." (Examiner's Answer, at pages 18 and 20). The Examiner refers the Board to Col. 9, lines 1-18 of Strobush. Again, the Examiner misrepresents what Strobush actually says. Strobush defines the evaporable liquid vehicle as a "solvent". Strobush does not use the term "water" to describe his solvents. The only solvents taught for use in Strobush are organic solvents, specifically 2- butanone and methanol (see example 1). There is nothing in Strobush that suggests his process be used on aqueous systems. Indeed, Strobush indicates that an aqueous system, which is prone to blistering, is subject to a mechanism of action that is different from mottle. (Strobush; Col. 3, line 58 to Col. 4, line 8). Specifically, as stated by Strobush, "[t]he formation of mottle occurs due to a different mechanism than blisters and requires different methods of control and elimination." (Strobush; Col. 4, lines 6-8).

Although Strobush comments in his background that mottle can occur with certain aqueous coatings, he does so in the context of differentiating the differences between water-based and solvent-based coatings and specifically distinguished the drying of solvent-based coatings from the drying of water-based latex paint coatings. (Strobush; Col. 3, line 58 to Col. 4, line 9). Thus, the Examiner's reliance of such disclosure on the background is equally inappropriate.

The Examiner repeatedly relies on Strobush's disclosure of "a wide variety of coatings", however, all of the "other coatings" referred to in Strobush are non-ingestible, organic solvent-based systems. There is no suggestion in Strobush of its applicability to aqueous-based systems,

let alone **ingestible** aqueous-based systems. In fact, a fair reading of Strobush clearly indicates that organic solvents, not water, are intended to practice his process.

Furthermore, there is nothing in Zerbe that speaks of a mottle problem. Accordingly, there is absolutely no suggestion to utilize the mottle-reducing drying method of Strobush (Strobush; Claim 1, Col. 22, line 16), to dry the edible aqueous-based films of Zerbe. Absent a suggestion or compelling motivation to combine the teachings of the references, the Examiner's rejection must be reversed. *See* MPEP §2143.01.

The Examiner's improper use of Appellants' disclosure to arrive at a conclusion of obviousness is most apparent when one considers dependent claim 95, which limits the wet film thickness to "at least about 500 μm ". Appellants' film thickness is **five** times greater than that exemplified by Strobush. **The Examiner has dismissed this difference in thickness without really thinking about what the difference means.** Zerbe's coating method is, like Appellants', directed to aqueous polymeric solutions. In contrast, Strobush is directed to organic solvent-based systems. Water vaporizes at 100°C and has a heat of vaporization of about 540 calories/gram. Strobush's exemplary solvent, methyl ethyl ketone, vaporizes at only 78.2°C and has a heat of vaporization of only 106.0 calories/gram. Not only is Appellants' coating five times thicker, but because it is aqueous, it also takes a significant amount more energy to vaporize the water contained therein than if the coating were based on a highly volatile organic solvent such as methyl ethyl ketone.

It must be remembered that the process of Strobush is designed to prevent rapid evaporation of an organic solvent and thereby prevent mottle. To this effect, Strobush created a dryer with a plurality of zones (which are divided into a plurality of sub-zones) and controlled the drying conditions within the zones such that the conditions in each zone were different. To control mottle, Strobush carefully controlled the difference in temperature (ΔT) between the temperature of the drying gas in contact with the coating and the temperature of the coated

substrate in each sub-zone. Strobush sought to adjust the heat rate such that it remained “at or below the maximum allowable or threshold heat transfer rate” such that the temperature of the coated substrate **slowly** increased over the length of the drying zone to prevent mottle. (Strobush; Col.15, lines 54-57). The maximum allowable heat transfer rate for Strobush is noted as 150 cal/sec-m². (Strobush; Col. 13, lines 57-66, Fig. 14). Strobush even appears to favor a coating “having less thickness” because this “would have a higher maximum allowable or threshold heat transfer rate”. (Strobush; Col. 13, lines 14-16).

When one considers that the aqueous solvent used in Appellants’ coating has a significantly higher vaporization temperature and a significantly higher heat of vaporization than the organic solvent (methyl ethyl ketone) used by Strobush, and when one further considers that the 500 μ m thickness of Appellants’ coating necessarily contains a lot more solvent (aqueous) than the 100 μ m thickness coatings of Strobush, the Examiner’s combination of Strobush and Zerbe in attempt to obtain the claimed process is even more nonsensical. This is because the process of Strobush, with its low heating rate, would require an apparatus of significantly greater length than practical, if the apparatus would work at all. Moreover, a number of Appellants’ method claims require the heating be such that the visco-elastic film is formed rapidly. Whereas Strobush teaches the gradual increase in ΔT to prevent mottling, such a slow increase would not allow the rapid build-up of visco-elastic properties required by Appellants to obtain uniformity of content. Strobush’s slow increase in ΔT is required for the prevention of mottle, whereas Appellants’ rapid build-up of visco-elastic properties necessarily involves a rapid increase in ΔT for rapid evaporation of water. This encourages uniformity of content within Appellants’ active-containing film. In view thereof, it is evident that the Examiner’s motivation to combine the teachings of Zerbe and Strobush improperly relies on hindsight afforded by Appellants’ own disclosure. *See In re Paulsen*, 30 F.3d 1475, 1482, 31 U.S.P.Q.2d 1671, 1676 (Fed. Cir. 1994).

- b. The Examiner's alleged suggestion or motivation to combine Zerbe, Strobush and Horstmann, as well as any tertiary references, is improper

Finally, at page 25 of the Examiner's Answer, the Examiner responds to Appellants' argument that U.S. Patent No. 5,629,003 to Horstmann et al. (hereinafter "Horstmann") does not suggest drying from the bottom. The Examiner asserts that one cannot show nonobviousness by attacking references individually. The important point to note, however, is that Horstmann and Zerbe are the only two references relied on by the Examiner to show the preparation of an edible film based on a solution or dispersion of a polymer in an aqueous base. Both of these references merely give a general disclosure of a conventional drying oven with no indication of any problems relating to drying. As such, there is no reason to look to other art, much less art relating to a complicated organic solvent-based process. Absent Appellants' own disclosure, there is no reason, suggestion or motivation emanating from the prior art to combine the teachings of Strobush with the teachings of either Zerbe or Horstmann. Similar to the Zerbe/Strobush combination, Horstmann is simply not combinable with Strobush. On this point, the Board should recognize that Horstmann describes a process wherein the drying of a 500 μm film is carried out at 80°C for 15 minutes. (Horstmann; Col. 5, lines 1-3). Essentially this same temperature was specifically taught against by Strobush. (Strobush; Col. 21, line 60, Tables 8, 9, Example 4-1, where 82.2°C was unacceptable due to high mottle rating).

- c. The Examiner fails to consider the Strobush reference as a whole

The Examiner also continues to improperly select only the bottom drying element from Strobush's complicated drying disclosure. In particular, at page 23 of the Examiner's Answer, the Examiner advises:

In response to appellants argument of appellants' rapid bottom heating causes a different phenomenon to take place, the examiner disagrees since both the appellants' and Strobush are drying the coating by heating the bottom of the coated substrate, the examiner is taking the position that the same phenomenon will take place.

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In reality, different phenomena will take place due to the wholly different systems involved. The aqueous-based polymeric systems of Appellants' claims will undergo different phenomena upon drying than the volatile organic-solvent based systems of Strobush. Such differences are described in detail in the Rounds Declaration. The Examiner has totally disregarded the potential effects of such significantly different materials. Moreover, in selecting only the bottom heating element from Strobush, the Examiner is ignoring all of the other pieces of Strobush's process that are vital to how it functions to incrementally dry organic-based coatings. The Examiner has thus divorced a single drying step from the complicated process of Strobush, and in doing so has improperly ignored the teachings of the Strobush reference as a whole. *See In re Wesslau*, 353 F.2d 238, 241, 147 U.S.P.Q. 391, 393 (C.C.P.A. 1965).

d. The cited art fails to yield all of the limitations of claim 117

The Examiner continues to improperly assert that the hypothetical combination discloses all of the limitations of Appellants' claim 117. In particular, claim 117 includes a combination of four very specific preliminary method steps prior to drying the film: (1) forming a masterbatch premix of a water-soluble polymer and water; (2) deaerating the premix; (3) feeding a predetermined amount of the deaerated premix to at least one mixer; and (4) adding an active to the at least one mixer.

Throughout prosecution, the Examiner continued to join claim 117 in with various other claims in formulating his obviousness rejection, without ever specifically delineating any reasoning or pointing to any specific passages in the cited art with respect to these preliminary steps. Now, for the **first time** in the Examiner's Answer, he provides his reasoning as to the preliminary method steps outlined in claim 117. The passage he relies on, however, fails to teach or suggest Appellants' specific combination of steps.

Specifically, the Examiner directs the Board to Col. 6, lines 1-56 of Zerbe. Therein, Zerbe forms a first premix of water and two modified starches. Zerbe also forms a second

premix of water and hydroxypropyl celluloses. Zerbe then simply combines these two solutions, adds a surfactant and then adds a flavor. Nowhere in this disclosure is there any teaching at all of Appellants' specific combination of preliminary steps. In particular, Zerbe does not form a **single masterbatch** premix, **deaerate** such masterbatch premix **prior to addition of an active** component, feed a **predetermined amount** of such deaerated masterbatch premix to a **secondary mixer** and **then add the active**. The Examiner's reliance on Zerbe for Appellants' specific combination of preliminary process steps is therefore misplaced. The combination of steps comes only from Appellants' own disclosure.

In sum, there is no motivation to combine the cited art, particularly the teachings of Strobush, Zerbe and, for some claims, Horstmann. Additionally, in formulating the obviousness rejections based on these references, the Examiner has improperly relied on Appellants' own disclosure. Moreover, the Examiner has over-generalized the disclosure of Strobush and failed to consider the teachings of the reference as a whole.

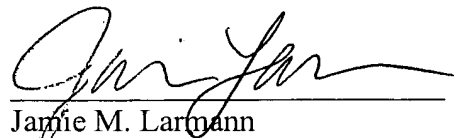
D. Conclusion

Zerbe is the primary reference relied upon by the Examiner for forming an edible film. Zerbe is completely devoid of any disclosure or suggestion of Appellants' claimed drying method for forming an active-containing film having uniform content. Although the Examiner refers to Strobush for such disclosure, Strobush is nonanalogous art and not properly combinable in formulating a rejection of Appellants' claims. Even if the Board were to find Strobush analogous, however, the Examiner has not shown motivation to combine the teachings of Zerbe and Strobush as suggested. The Examiner has relied on his own unsupported assumptions in attempt to establish motivation to combine the references. In this regard, the Examiner has not even addressed the Declaration of an expert indicating why Strobush is not analogous to Appellants' claimed invention and why Appellants claims are not obvious. The cited tertiary references do not overcome the deficiencies of Zerbe and Strobush. In conclusion, claims 91, 93-104, 106, 108-112, 114, 116, 117 and 119 are patentable.

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Favorable action is earnestly solicited and a finding of patentability of claims 91, 93-104, 106, 108-112, 114, 116, 117 and 119 is respectfully requested.

Respectfully submitted,

A handwritten signature in dark ink, appearing to read 'Jamie M. Larman', is written over a horizontal line.

Jamie M. Larman
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EXHIBIT A

Use information: This paragraph is informational only and is not exclusively definitive of the end use.

For face and back offset printing of long run books, pamphlets, magazines, periodicals, brochures, etc. Printed matter may include text, line illustrations, and halftones up to 150-line screen.

Stock: Not less than 10 pct postconsumer fiber. Any percent over 10 percentage points, is encouraged, provided that the requirements of this Standard are met.

Acidity: pH value of coating shall average not less than 6.5.

Grammage (g/m²) 55
Basis weight: 25 by 38 inches, 500 sheets (pounds) 38
A tolerance of ± 5 pct shall be allowed.

Bursting strength: Average, not less than (kPa) 70
Equivalent (lb/in²) 11

Opacity: Average, not less than (percent) 89
No individual specimen shall average less than (percent) 87

Thickness: Average (mm) 0.055
Equivalent (inch) 0.0022
A tolerance of ± 0.013 mm (0.0005 inch) shall be allowed.
Paper shall be uniform and shall not vary more than 0.011 mm (0.0004 inch) from one edge to the other.

Gloss (75°): Average, each side, not less than (percent) 40

Smoothness of coating: Average, each side, not to exceed (units) 65

General appearance: Paper shall conform to the standard sample(s) adopted by the Government.

Color: The paper in the order (or publication) shall be uniform with the brightness not less than 70 pct. The color variation shall not exceed DE(CIELAB)=1.0.

Formation: Shall be uniform. The coating shall be uniformly applied; shall not be gritty, mottled, stippled, or ribbed in appearance; and shall not crack or flake off.

Cleanliness: The dirt count for each side of the paper shall not exceed 100 specks per square meter. No sample sheet (600 to 650 cm² in size) shall contain more than one defect with an equivalent area of 0.25 mm² or greater.

Sampling and testing: Shall be conducted in accordance with standards in Part 2, *Government Paper Specification Standards*.

Unless otherwise specified, the following is automatically waived when printing or duplicating is to be accomplished on commercial contract

Tensile strength: Average, not less than—
Machine direction (kN/m) 1.7
Cross direction (kN/m) 0.9
Equivalent—
Machine direction (kg/in) 4.2
Cross direction (kg/in) 2.2

Color: Shall match the Government's standard sample for color. A deviation of DE(CIELAB)=3.0 from the color standard is allowed.

Curl: Paper shall lie flat with either no tendency to curl or with a curl which can be overcome under reasonable working conditions.

Coating and surface: Shall be uniform, free from mottle and any particles which will pick, lift, or pile on the blanket under normal press conditions.

Size and trim: Rolls: Roll width and diameter shall be as ordered. A tolerance of ± 2 mm ($\frac{1}{16}$ inch) shall be allowed for width and ± 26 mm (1 inch) for diameter.

Roll winding: Roll paper shall be tightly wound at even tension and shall not contain more than the specified maximum number of splices per roll. The number of splices permitted per roll is determined by the roll diameter as ordered. On rolls 1,016 mm (40 inches) or less, a maximum of three splices per roll shall be allowed. On rolls over 1,016 mm (40 inches), a maximum of four splices per roll shall be allowed. Splices shall be neatly and securely overlap-pasted and made with a repulpable adhesive which will not permit the splice to separate. The adhesive may be applied from a tape form backing, provided the backing is removed, leaving only the adhesive component on the splice. The adhesive shall not cause the splice to adhere to adjacent laps. The tails of the splices shall be neatly and evenly removed without damage to adjacent laps. Splices shall be flagged at both ends with projecting colored markers, not pasted to the splice, or otherwise clearly marked.

Pressroom conditions: The bulk of this paper will be used in air-conditioned pressrooms maintained at 24°C $\pm 2^\circ\text{C}$ and 45 pct ± 8 pct relative humidity.

Use information: This paragraph is informational only and is not exclusively definitive of the end use.

This paper is used for the photographic masking process and for face and back offset printing.

Stock: Free from groundwood or unbleached pulp.

*Note:*¹ Postconsumer fiber, in any percentage, is encouraged, provided that the requirements of this Standard are met.

Equilibrium relative humidity: Shall be 45 pct \pm 8 pct at 23°C \pm 2°C.

Grammage (g/m²) 120
Basis weight: 25 by 38 inches, 500 sheets (pounds) 80
A tolerance of \pm 5 pct shall be allowed.

Bursting strength: Average, not less than (kPa) 140
Equivalent (lb/in²) 21

Coating: Shall be uniformly applied; shall not be gritty, mottled, stippled, or ribbed in appearance; shall not crack or flake off.

General appearance: Paper shall conform to the standard sample(s) adopted by the Government.

Color: The paper in the order (or publication) shall be uniform and match the goldenrod standard. The color variation shall not

exceed DE(CIELAB)=1.0. The CIELAB values (Ill D65, 10° observer) of the color standard are

L^* =78.0 to 82.0

a^* =9.5 to 13.5

b^* =67.0 to 71.0

Light transmission: Shall not exceed 0.1 pct at wavelengths below 540 nanometers and 4.5 pct at wavelengths from 540 to 700 nanometers, as measured spectrophotometrically.

Finish and formation: Shall be uniform.

Cleanliness: The dirt count for each side of the paper shall not exceed 50 specks per square meter. No sample sheet (600 to 650 cm² in size) shall contain more than one defect with an equivalent area of 0.25 mm² or greater.

Sampling and testing: Shall be conducted in accordance with standards in Part 2, *Government Paper Specification Standards*.

Unless otherwise specified, the following is automatically waived when printing or duplicating is to be accomplished on commercial contract

Curl: Paper shall lie flat with either no tendency to curl or with a curl which can be overcome under reasonable working conditions.

Surface: Shall be uniform, free from mottle, and any particles which will pick, lift, fluff, or pile on the blanket under normal press conditions.

Size and trim: Sheets: Paper shall be furnished in the size(s) ordered and shall be flat, trimmed square on four sides with clean smooth edges, and evenly jogged. A tolerance of \pm 2 mm ($\frac{1}{16}$

inch) shall be allowed except for sheets 216 by 356 mm (8½ by 14 inches) or less; then a tolerance of \pm 1 mm ($\frac{1}{32}$ inch) shall be allowed. Successive sheets within any package shall not differ from each other by more than 0.5 mm ($\frac{1}{64}$ inch). Paper with the long dimension 813 mm (32 inches) or less shall be considered square if the variation does not exceed 1 mm ($\frac{1}{32}$ inch); over 813 mm (32 inches), 2 mm ($\frac{1}{16}$ inch).

Grain: Direction of the grain on flat paper shall be as ordered.

¹This grade is typically a low Government usage paper and currently not readily and/or economically available with postconsumer fiber content.

Mottle Measurement of Wet Trap, Back Trap and Other Motley Images

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Abstract

A single objective mottle measurement is described that relates to the full subjective range of visible mottle from "Graininess" to "Patchiness" and multi-color "Wet Trap" to produce a single number ranking mottle within both large and small areas.

This new algorithm responds uniformly to all levels of visually apparent mottle in digital images of printed matter and those obtained by optical transmission for paper formation measurement. Any digital image of sufficient resolution to visibly display the mottle pattern may be used with the method. When set to do so, it also measures sub-visible mottle found in pitted solid print areas.

Mottle is usually a subjective measurement without uniform criteria for ranking specimens. To minimize the subjectivity the author has provided examples of the new algorithms use in two applications where the mottle has been created under controlled conditions. These applications produced expected mottle that when measured using the new method demonstrate its viability.

In an effort to achieve consensus on a common mottle measurement technique that works under all conditions the underlying logic and mathematics are disclosed.

Introduction

This method was developed in response to an immediate need for a reliable, reproducible mottle measurement that provides a single ranking number correlated to the full range of visual mottle. ISO 13660 5.3 and 5.4 are attempts to provide separate numbers for fine mottle, "Graininess", and coarse mottle, "Patchiness". As will be demonstrated, both ISO numbers fail to measure properly under most real operating conditions.

The algorithm satisfies the paper industry need to have a solid method of measuring optical formation and calender blackening. It also provides the print industry means to measure visual mottle in large areas for such applications as back trap mottle, wet trap mottle, IGT and Prufbau tests. As a result the application base for the algorithm is extremely wide.

What is Mottle?

Mottle is usually a subjective evaluation without formal guidelines or other criteria for ranking. It appears to be based upon several criteria:

In a monochrome image:

1. The overall degree or severity of contrast between light and dark areas.
2. The sizes of the contrasting areas.
3. Spatial distribution of the contrasting areas.

In a polychromatic image:

1. Variation in the relative intensity of the colors present.
2. The sizes of the colored areas.
3. Spatial distribution of the colored areas.

The applications, and the work that follows, concentrate upon the polychromatic motley image. These images are usually the result of multiple inks of different colors being printed in the same area as solids or half-tones.

Color Extraction – Wet Trap Mottle

Digital Color Image Requirement

The human eye detects mottle as non-uniform distribution of colors and shades. The most common form of mottle occurs in a printed image when two inks are printed one over the other, as in offset print wet trap. If the deposition of the inks in a solid print area is not perfectly uniform the eye will see a two color mottle. As a result one of the most important aspects of mottle analysis is the color content of the digital image to be analyzed.

Most cameras and scanners used in the industry will acquire full color, Red, Green and Blue (RGB), 24 bit, digital image. For further processing in mottle measurement, the commonly used techniques will convert these 24 bit color images into an 8 bit grayscale image. Because each of the original color intensities is acquired using the same digital scale and converted to a single virtual monochromatic grayscale image, the conversion loses essential information about the mix of color luminance intensities present in the original image.

To replicate a mottled color balance, the new mottle measurement method also uses a 24 bit, RGB, color image of the mottled area as a basis for measurement. The 24 bit image is actually composed of three images, one for each of the color RGB bands. Each of these three color band images is 8 bits deep having a range of luminance values for each pixel from 0 (Black) to 255 (white) or 256 shades of gray that are analogous to the intensity of the light striking that particular sensor in the imaging camera.

These color bands may be extracted to display and analyze specific color reflectance and absorption characteristics of the inks used in the original image.

An example of this split is shown in Fig.1. Color band separation and recombination is useful in evaluating solid print areas in pure cyan (C), magenta (M), yellow (Y) and black (K), and, as will be demonstrated, it is an especially valuable tool in the evaluation of "wet trap" where the same area is overprinted with different color inks.

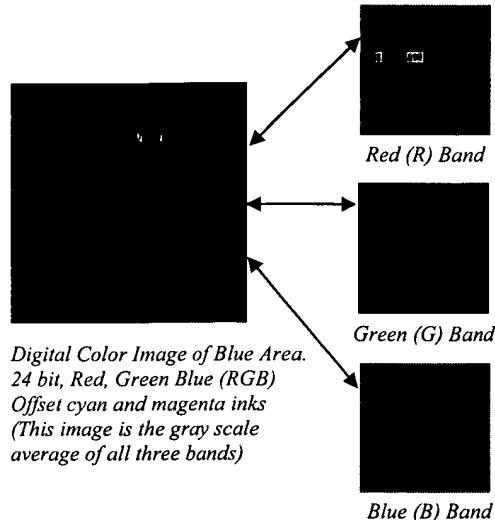


Figure 1: A digital color image as acquired by a camera or scanner is composed of three separate color bands. The pixel luminance value in each band varies from 0 (100% absorbed) to 255 (100% reflected). Thus the blue shows as the lightest gray tone. The red image shows the effects of the magenta mottle. When extracted as a single grayscale image, as shown in the original large area, these bands are averaged together at each pixel location.

Polychrome Mottle – Wet Trap Mottle

The need for color band separation and recombination is illustrated in a printed example of a conventional blue color. To print a blue color the printer first lays down a cyan ink and then overprints it with a magenta ink. If the properties of the paper, ink or press are not correct the result will be a motley blue with patches of magenta and cyan showing up in varying degrees.

Figure 1 shows a motley blue. It is a wet trap print of cyan and magenta inks split into its separate red, green, and blue color image components. So that it can be reproduced here as an uncolored print, it also shows the result of averaging together all the color bands to produce a gray scale image. If the reflected intensities of all the colors are the same, or very close, as is the case in this example, the averaging technique will not produce a grayscale image representative of the polychromatic mottle.

For example, the magenta and cyan inks used to create a blue image can reflect similar luminance intensities at different wavelengths specific to their color. In the camera or scanner, the filters on the red, green, and blue sensors will pass light only in their specific wavelength ranges and will respond proportionally to the luminance intensity received.

Thus, in the extreme, a mottled image of cyan and magenta inks could, under certain conditions, produce a uniform gray scale image.

This problem is simply addressed by summing only the luminance values from the specific red, green and blue color bands that are reflected from the ink colors used in the original color image. The summed bands are then used to create separate virtual images specific to the inks used in the image prior to analysis.

CMYK Color Extraction

The cameras and scanners used to acquire digital images of printed images contain three separate matrixes of sensors; Red (R), Green (G), and Blue (B). Each of these three is capable of producing a separate grayscale image of the original image content in its specific wavelength sensitivity.

In the most common printing system four basic ink colors are used; Cyan (C), Magenta (M), Yellow (Y) and Black (K). The color camera collects, as best it can, the full spectrum of reflected light subdivided into RGB as described above. It is possible to separate the RGB bands and recombine them to create a virtual image containing only those reflected colors primary in the ink color of interest. To extract the reflected colors collected by the RGB camera image the following combinations are used:

Green + Blue = Cyan reflectance
Red + Blue = Magenta reflectance
Green + Red = Yellow reflectance

Conversely, bands absorbed by these inks are:

Red = Cyan absorbance
Green = Magenta absorbance
Blue = Yellow absorbance

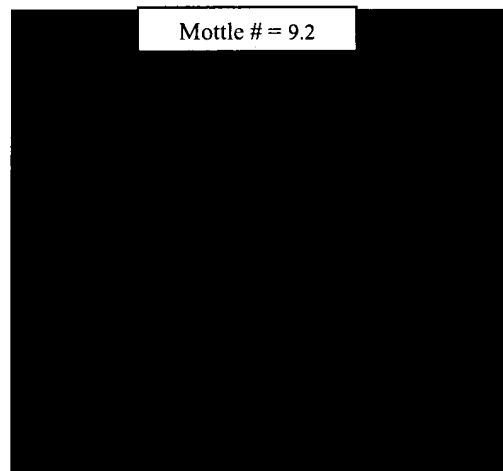


Figure 2: The gray scale image of a blue offset print made with magenta printed over cyan. The gray scale image is of the three 8 bit color bands averaged together to create this 8 bit image.

To draw conclusions about mottle in a polychromatic image, the human intellect evaluates the reflective intensity and spatial distribution of its colors. A solid

blue wet trap can appear to be purple at a distance because, when viewed at short range, it is actually a motley mix of cyan and magenta. Figure 2 shows a typical grayscale image of a motley magenta/cyan blue. Because it has low contrast, any analysis based upon variances in luminance values in this averaged image will produce indeterminate results.

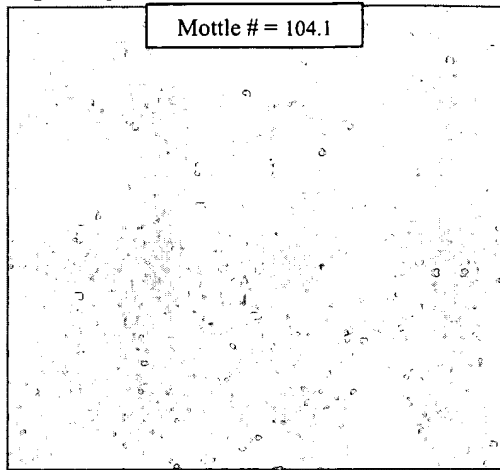


Figure 3: Cyan reflectance grayscale of the blue offset print shown in Fig.2 created by summing the green and blue bands from the original color image. Note the visibly higher contrast over the average of the bands shown in Fig 2.

Color Reflected, Color Band Summing

As described above, the reflective RGB image components specific to the reflected wavelengths of the ink color of interest in the original print can be recombined as a sum. The summing creates a new virtual image of the selected ink. Typical images of cyan and magenta extracted from a motley magenta/cyan blue are shown in Figures 3 & 4. These images clearly demonstrate a higher contrast than the average of all bands shown in Figure 2.

Color Absorbed

When printed as a solid area, the yellow ink normally has a very high reflectivity. Almost all of the red and green light striking it is reflected providing only the smallest of variance due to mottle. As a result, summing the red and green bands will produce a very low contrast image that is almost free of variance. But, in most cases, the absorbed band, blue, can produce a good high contrast single band image of the mottle within a solid yellow.

Digital Resolution

The resolution or calibration of the digital image need only be sufficient to display on screen, at any magnification, the mottle pattern to be measured. High resolutions such as the 600 ppi recommended by ISO 13660 are not necessary unless the image is to be inspected for sub-visible mottle. Typical resolutions for the new method range between 100 and 300 ppi (sensors per inch, spi).

At high resolutions of 600 ppi and higher, the mottle measurement is responsive to sub-visible variations useful in determining the concentration of pits and pores in contact printed surfaces, ink jet striping and toner deposit variations. As will be explained below, the range of tile sizes selected by the investigator can limit the measurement to the sub-visible and exclude the visible targets and vice versa.

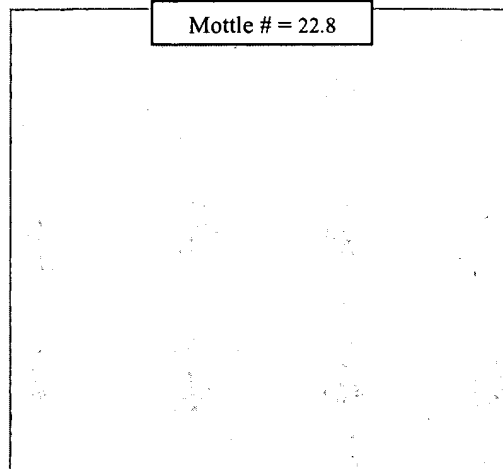


Figure 4: Magenta reflectance grayscale image of a blue offset print made from the sum of the red and blue bands. Note the lesser contrast than the Cyan extraction shown in Figure 3 but still greater than that shown in the average of all bands shown in Fig 2.

At 600 ppi (spi) the sensors in the camera are able to pick up reflections from areas as small as 42 micrometers in diameter. Nominally, the normal human can only see a pure black speck that is 50 micrometers in diameter against a stark white background using excellent illumination. Our work has determined a resolution of 300 ppi is sufficient to capture the image of mottled print and optical formation. At 300 ppi the sensor in the camera is gathering the light from an area 84 micrometers in diameter in much the same way as the eye would see this printed image at a short viewing distance.

Mottle Spatial Distribution

Fine to Coarse Mottle Profile, Tile Size Variation

The new mottle method employs a series of different size tiles that follow a binary dimensional progression. Each tile size is dedicated to a "Layer". Within each layer the tile is laid over the image in a pattern of non-overlapping contiguous tiles. As shown in Figure 5, this pattern is similar to that used in ISO13660 5.2.3 & 4. The mottle measurement made within each tile size layer is used to create a mottle profile of the range of tile sizes as shown in Chart 1. The average of all the layer mottle measurements becomes the mottle number for the image examined. The measurement profile and its average emulate the human intellect in its instantaneous evaluation of mottle in various spatial distributions.

All physical tile dimensions are based upon the original image pixel center to center distance. At high image resolutions, 600 ppi and above, the smaller tiles can contain sub-visible elements. Our work has determined a resolution of 300 ppi (spi), or even lower, is sufficient for most visible mottle evaluations.

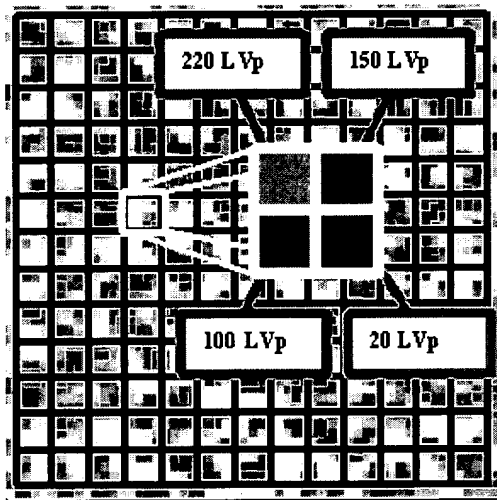


Figure 5: The basis for the new method is the 2 pixel x 2 pixel contiguous tile pattern shown in black. Shown in white is the extraction of a single tile with the contained pixel luminance values. (LVp).

Figure 6 shows the new method creates a controlled series of tile sizes based upon the image pixel resolution. The tile sizes always begin with a 2 pixel by 2 pixel tile as shown in Figure 5. This is the smallest tile. Starting with the smallest, the tiles progress in size changes following a binary progression (in pixels): 2 x 2, 4 x 4, 8 x 8 ... to a possible maximum of ten (10) sizes with largest possible being 1024 x 1024 pixels. The maximum tile size is set when the image dimensions cannot accept four contiguous tiles of the next tile size when both are measured in pixels.

Each tile size is assigned, in order, to a layer beginning with the first 2 pixel x 2 pixel tile. All calculations are made on, and reported for, each layer separate and independent from the others.

Tile Data Source – Successive Tile Sizes

The binary progression in tile sizes is used to determine the spatial variation component of mottle, fine to coarse. As explained above, the sizes are set using a binary progression starting with a 2 x 2 pixel tile and ending with the largest the image will accommodate. Each successive tile size is based upon the average of the pixel luminance values (LVp) in the preceding tile size. This averaging makes each successive tile size independent of variations among the pixel LVp in the preceding tile size. All tiles contain four (4) elements regardless of their physical dimensions or position in the layer sequence. This calculation is presented graphically in Figures 7 & 8.

Because it is based upon the average of the luminance value data in four contiguous tiles from the previous layer or, as in the first layer, pixels, each successive layer contains 25% of the number of elements as does the previous layer. The physical dimensions of the tile in the layer remain based upon the original image pixel dimensions.

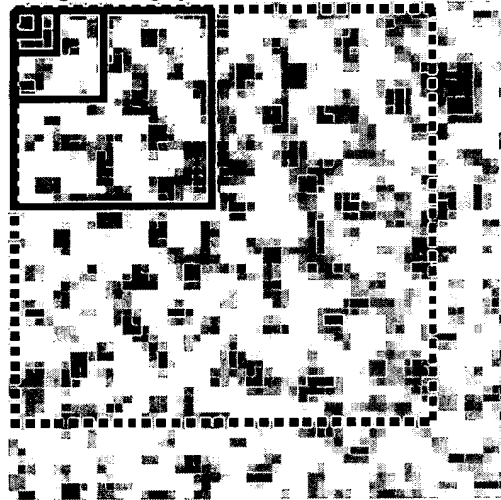


Figure 6: The first four tile sizes that would fit inside the image as shown. The new mottle method requires at least four of any one size inside the image. In this case only the first four sizes in the binary size progression will fit inside the image pixel dimensions. Following the rule that at least four tiles of a given size must fit, the fifth and larger sizes are not used

Frequency Leveling Between Layers

The effect of this progressive averaging of the luminance values in the 2 x 2 tile from one layer to the next is to level out the element to element luminance value transitions. This averaging tends to have the measurements in each layer independent of one another by removing the higher frequency transitions found in the previous layer.

Mottle Computation

The First Level Calculations – Data Bases

Figures 7 and 8 show graphically the two calculations made on each 2 x 2 tile: The percent difference among the elements in the tile and their average. The result of each calculation is stored separately in one of two data bases each of which is exactly ¼ the size of the original image as measured in elements.

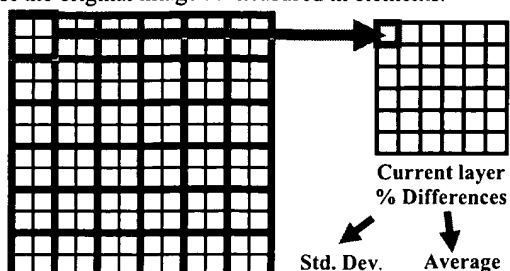


Figure 7: From the differences among the 2 element x 2 element previous layer create a data base to be used as the basis for the current layer mottle measurements. The standard deviation and average of these are two terms in the mottle calculation.

Data Base 1. Percent Difference Among Pixel LV

First, the method calculates the percentage difference among the pixel luminance values (LVp) within each tile pixel size based upon a 256 luminance value scale.

$$\text{PctDiff} = 100 \times \Sigma(\text{Abs}(\text{Diff}_{P1 \text{ to } P4})) / (6 \times 256)$$

Where: Diff_{P1 to P4} is the absolute arithmetic difference among the four(4) pixel luminance values in the tile. There are six(6) absolute differences: abs(1-2), abs(2-3), abs(3-4), abs(1-4), abs(1-3), abs(2-4).

As shown in Fig.7, these differences are recorded in a data base from which they are extracted for further calculation of the standard deviation among them and their average.

Data Base 2. Average of the Pixel LV

Then, as a second function, the average of all the pixel luminance values is calculated and stored in the database location for that tile.

$$\text{AveLV} = \Sigma_{1 \text{ to } 4}(\text{LVp}) / 4$$

Where LVp is the pixel luminance value

Data base 2 serves two purposes: First, as shown in Fig. 7, it is used in the mottle calculation for the tile pixel size under current evaluation and, second, it is used as the basis to create a virtual image or data base for the next layer or tile size.

Mottle Calculation for Each Tile Size

These two data bases are then used to calculate the mottle number for the layer. Each layer is dedicated to a specific physical tile size.

$$\text{Layer Mottle\#} = \text{SD}_{\text{Diff}} \times \text{AVE}_{\text{Diff}} \times \text{SD}_{\text{Averages}}$$

Where:

SD_{Diff} = Standard Deviation of Data Base 1

AVE_{Diff} = The average of Data Base 1

SD_{Averages} = Standard Deviation of Data Base 2

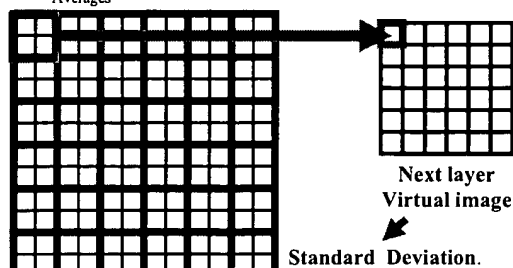


Figure 8: From the averages of the 2 element x 2 element previous layer create a new virtual image to be used as the basis for the next layer measurements. Each element of the subsequent layer is composed of the average of a 2 element x 2 element average of the previous layer. The standard deviation of the data in this layer is a term in the mottle calculation.

The New Mottle Number

The final mottle number is the arithmetic average of the individual tile size mottle numbers as calculated above.

$$\text{Mottle} = (\Sigma_{1 \text{ to } N}(\text{Layer Mottle \#})) / N$$

Where:

N = the number of layers or physical tile sizes

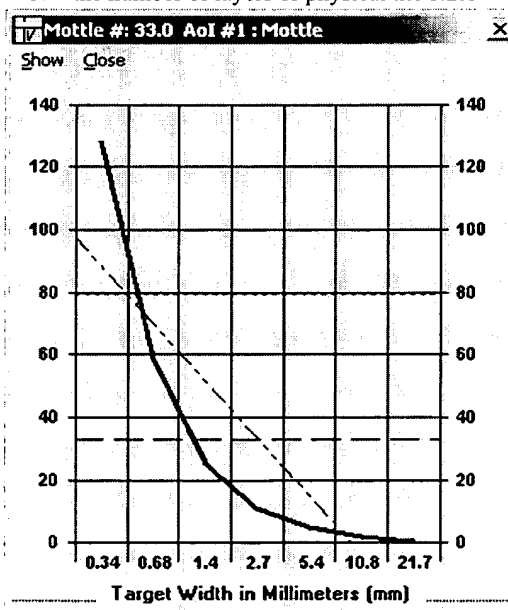


Chart 1: The mottle number in the upper left corner, 33.0 is the average of the individual mottle numbers for each of the seven (7) tile sizes or "Targets" shown in the chart.

Chart 1 shows a typical graph of the values obtained from the application of the new mottle method. In this example the largest size tile that would fit at least four (4) tiles in the image is 21.4 mm square and the smallest target is 340 micrometers square.

Applications

The new mottle algorithm is currently being used at the Rochester Institute of Technology (RIT), In Rochester New York. The offset print operations there evaluate paper, inks and on press technology variations for the general industry. The purpose of all evaluations is to report on the quality of the print.

Paper quality can vary across relatively large areas. There can be variations in performance from one square centimeter to the next. As a result the on press evaluations at RIT usually lay down print areas in excess of 10 sq cm and can be as large as 350 sq cm. The quantitative mottle measurement in these large areas must be reproducible and consistent across the complete spectrum of mottle patterns from what is normally classified as "Grainy" to that which is "Patchy".

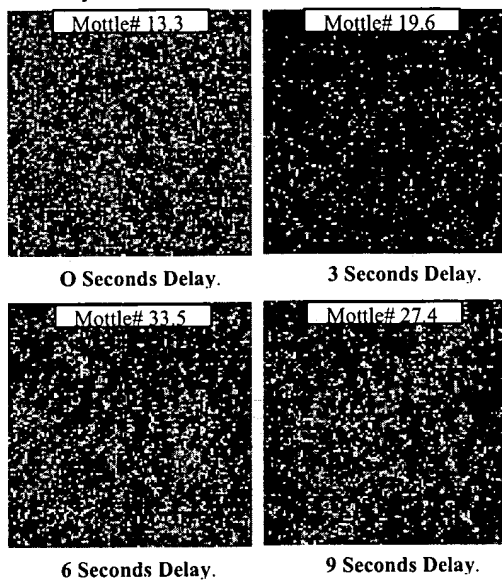


Figure 9: Magnified extractions from a series of IGT A5 test strips showing cyan ink overprinted at various time intervals. These images were extracted from the larger full scale images, magnified and contrast enhanced for reproduction here. The mottle numbers shown are for the full image un-enhanced.

IGT A5 Apparatus, Wet Trap Evaluation

A particularly definitive measurement is the IGT A5 test strip which is used at RIT to evaluate the wet trap performance of both ink and paper.

Mottled print is particularly difficult to show in this printed format so enhanced magnified images are shown in Figure 9. The measurements displayed in Tables 1 & 2 were not taken from these images but were obtained from the original full size images without enhancement.

As can be observed the inspectors agreed upon the ranking for the two best and two worst but disagreed upon the ranking within the worst category. The new mottle measurement agreed with two of the three inspectors on all rankings.

The ISO measurements did not agree with any rankings except by eliminating the specimen with the best appearance by all criteria!

| Delay | 0 Sec | 3 Sec | 6 Sec | 9 Sec |
|------------|-------|-------|-------|-------|
| New Mottle | 13.3 | 19.6 | 33.5 | 27.4 |
| ISO Mottle | 2.7 | 1.4 | 2.8 | 2.2 |
| ISO Grain | 143 | 130 | 136 | 134 |

Table 1 Various mottle measurement methods applied to overprinted cyan ink using an IGT A5 at various time delay settings between the initial print and the overprint.

| Delay | 0 Sec | 3 Sec | 6 Sec | 9 Sec |
|---------|-------|-------|-------|-------|
| Insp. 1 | 1 | 2 | 3 | 4 |
| Insp. 2 | 1 | 2 | 4 | 3 |
| Insp. 3 | 1 | 2 | 4 | 3 |

Table 2: The IGT test shown in Figure 9 and evaluated in Table 1 as ranked by three inspectors. All inspectors agree that 6 & 9 seconds delay are the worst.

RIT Back Trap/Water Interference Evaluation

This is an offset press evaluation for the performance of paper printed at two different units of the press to determine how well the paper fixes the ink prior to multiple blanket exposures. It also will indicate if the paper is properly absorbing the water after multiple unit exposures prior to printing on the last unit of the press.

Visual Criteria - Back Trap/Water Interference

The interesting aspect of this evaluation is the comparison between two very large printed areas that were created with the specific intention of having different mottle patterns. The specimen from unit 2 has received multiple blanket exposures with no further applications of ink before it comes off the press. Whereas the specimen from unit 6 has experienced multiple water exposures before it receives an application of ink and has had no blanket exposures. With a given paper the two mottle patterns should be distinctly different.

| New Mottle | 1 | 2 | 3 | 4 |
|------------|-----|-----|-----|-----|
| Unit 2 | 207 | 199 | 260 | 220 |
| Unit 6 | 89 | 60 | 47 | 84 |
| Difference | 118 | 139 | 213 | 136 |

Table 3: Back trap mottle / water interference; Solid cyan printed at unit 2 and unit 6 in areas 165 mm x 236 mm. Shown are results of the new mottle algorithm measurement.. The specimen order is the visual ranking of unit 2. Unit 6 was not ranked visually and is presented to as a basis of comparison; the last unit printed should have much less mottle than unit 2.

If the mottle is greater on unit 6 than that on unit 2 the paper is subject to water interference. A difference in the mottle patterns is readily apparent in this evaluation and by visual inspection none of these

specimens indicated the presence of water interference. As a result the specimens were subjectively ranked only for back trap mottle on unit 2.

Objective Measurement

Table 3 shows the visual ranking of the 2nd unit mottle pattern. There is complete agreement between the two worst and two best specimens but the order of rank is reversed for the two worst. This is not an unusual event in subjective mottle evaluations.

The important aspect of the measurement is the comparison between unit 2 and unit 6 where the intention is to create a difference. The new method demonstrates its ability to clearly distinguish between the two to a degree that is visually confirmed.

As shown in Tables 4 & 5 the ISO 13660 techniques are unable to measure mottle in this same set of specimens.

| ISO Mottle | 1 | 2 | 3 | 4 |
|------------|----|----|----|----|
| Unit 2 | 21 | 22 | 21 | 22 |
| Unit 6 | 30 | 23 | 15 | 25 |
| Difference | -9 | -1 | 6 | -3 |

Table 4: ISO 13660 Mottle applied to same specimens as shown in Table 3. The difference between the two measurements is almost in total disagreement with the known differences between the specimens.

| ISO Graininess | 1 | 2 | 3 | 4 |
|----------------|-----|-----|-----|-----|
| Unit 2 | 317 | 316 | 314 | 315 |
| Unit 6 | 305 | 319 | 312 | 314 |
| Difference | 12 | 3 | 2 | 1 |

Table 5: ISO 13660 Graininess applied to same specimens as shown in Table 3. The difference between the two measurements is almost non existent.

Summary

The new mottle calculation has been proven to work in a variety of mottle evaluations. It closely emulates the human ranking of a variety of specimens by:

1. Providing a means of separating and recombining the color bands in the original color image to reconstruct the original ink reflected or absorbed values. Thus, the method is able to measure multi-color wet trap mottle and low density images.
2. The construction of successive image layers using the average of the picture elements or luminance data tile size from the previous layer provides a measure of mottle spatial distribution for each layer independent of the preceding layers containing smaller tile sizes.

3. Providing a means of adjusting the mottle measurement to the resolution of the image evaluated in order to set the mottle evaluation to the visible range.
4. The calculation of a coefficient proportional to the number and intensity of the tile element transitions present in the tile size evaluated. The tile size mottle number is calculated based upon both this number and applied to the variance among the average of these same tile elements.
5. The calculation of the average of all individual tile size mottle numbers to report the new mottle number for the image area evaluated.

The new mottle method has demonstrated its ability to objectively measure mottle in large and small printed areas.

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Daniel Clark of the Rochester Institute of Technology in Rochester NY, USA conducted on machine evaluations of a staggering number of revisions to this software prior to its being the finished and working algorithm described above.

Christine Canet of the Quebec Institute of Graphic Communications in Montreal Quebec, Canada also conducted a large number of trials of this algorithm to confirm its ability to conform to visual ranking of both printed specimens and calender blackening.

BACK-TRAP AND HALF-TONE MOTTLE MEASUREMENT WITH STOCHASTIC FREQUENCY DISTRIBUTION ANALYSIS

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ABSTRACT

A spatially sensitive stochastic frequency distribution analysis software algorithm, operating in a graphic arts quality scanner based image analysis system, has been applied to offset printed images. This algorithm is based upon the luminance value statistical variance within a target that is "tiled" in the image as opposed to other less reproducible techniques that employ the average of the luminance values. The algorithm is sensitive to the spatial distribution and relative size of skipped and lightly printed sub-visible areas that are correlated to half-tone mottle. It has been discovered the separation and arithmetic recombination of the digital image color bands used to acquire the digital image can be used to amplify the variances in different colored inks. Several examples of this method in use are provided with illustrations and a suggested measurement scale.

INTRODUCTION

Mottle is the non-uniform reflection from a surface or transmission of light through a translucent specimen. When the human eye inspects a mottled surface it recognizes changes in the luminance from one area to another. Small repetitious areas that have a consistent variation within them are called "Texture. The uniformity of the texture distribution, or degree of mottle, can vary across a wide range of spatial frequencies. Human cognition occurs when the intellect determines which mottle pattern forms specific images of interest. At any level of magnification, it is the spatial distribution of the transitions from one luminance level to another, or texture distribution variations, that determines the degree of mottle.

In the inspection of printed images containing half tones the current practice is to evaluate mottle by directly measuring the circularity, size, and luminance value of the discrete printed dots. An attempt is then made to relate these measurements to mottle. Because of the high resolution and magnification required, the apparatus currently employed in dot measurement examines only relatively small printed areas. As a result of the small areas of examination and the errors associated with exact dot size measurement it is difficult for the papermaker to correlate these results to process variations that impact large areas of the sheet.

Printed areas occupy thousands of square meters and, among other criteria, paper and film print quality is based upon the uniformity of ink transfer across the entire printed surface. Mottle can occur in spatially diverse areas. As a result, It can be inferred that the evaluation of large images is better than small in detecting and measuring mottle. The automated image analysis method discussed in the following can measure mottle in large areas as well as small.

STOCHASTIC FREQUENCY DISTRIBUTION ANALYSIS

Stochastic derives from the Greek word "stokhos" for the pillar or stake used in ancient times as a target for archers. Stochastic Frequency Distribution Analysis (SFDA) employs a contiguous virtual matrix of small square digital target areas within a digital image. All digitized images are composed of picture points that accrue to themselves the characteristics of the pixel or picture element to be printed or displayed and the dimensions of the square target are also expressed in picture points (pp). As shown in Fig1, the matrix of targets covers the entire area to be inspected and subdivides it into a uniform pattern of targets each containing exactly the same number of image picture points. In the SFDA the degree of variation among the picture point luminance values within each target and the variation among the targets themselves determines the degree of mottle.

A very small target, for example, could contain 25 pp. At 500 ppi this small area is visible and is what the eye would recognize as the texture of an image. Its numeric value is the pp luminance value variance. As shown in Fig1, these texture measurements are then grouped into larger targets and the variance of the textures within the larger targets then used to compute the variance among the larger targets which is then a measure of the spatial distribution of the patterns formed by the image texture. By using a range of target sizes based upon the underlying texture, SFDA provides a measure of mottle spatial distribution.

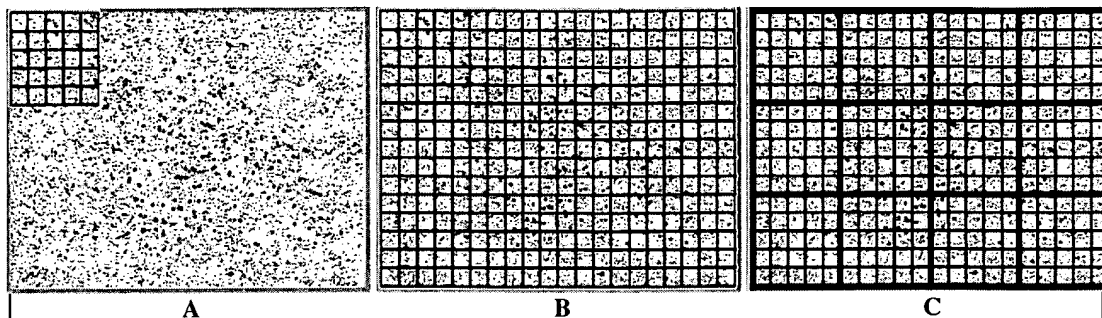


Figure 1 Stochastic Frequency Distribution Analysis: The statistical variance of the luminance values for all picture points within each of the small targets shown in A & B is computed and recorded in a matrix data base of the same dimensions as the target matrix. The overall texture of the image is proportional to the variance of the variances in the small targets shown in B, a total of 300. These individual variances are then grouped into targets containing the same number of smaller target variances, in this case 25 each. The variances of the variance of 25 small targets in each of the larger targets in C, a total of 12, is recorded in another data base where the variance of those variances is now proportional to the spatial distribution of the image texture.

The sensitivity of this measurement technique is proportional to the resolution of the image and the smallest target used to define the texture. The resolution can be quite coarse and the measurement will still respond to changes that are very fine by comparison. For instance, to predict half-tone mottle, an image of a solid black area can be acquired at 500 ppi and measured with a target that is 254 micrometers square containing 25 picture points. At 500 ppi the picture point sensor is gathering light from an area that is 0.0508 mm in diameter, slightly larger than the offset dot 30 micrometers diameter. Because of the high contrast between the black ink and the paper, any pore or void in this solid black image will change the luminance value of the picture point receiving the light from the pore proportional to the size of the pore. Since the picture point is part of the 25 picture points within the target, the luminance value statistical variance for that target will be changed. The variance of the variances among all the targets covering the image area then provides the mottle at a spatial distribution determined by the target size.

Target Size for Tests

Unassisted, the human eye can detect variations in luminance values in areas smaller than 1 mm square. When inspecting for visible image variations such as half-tone mottle it is therefore advisable to relate the visible to the sub-visible by measuring at a variety of spatial distributions at least one of which is visible. For half-tone mottle it was determined experimentally three target sizes with widths and heights of 5 pp (0.25 mm), 20 pp (1.0 mm), and 40 pp (2.0 mm) worked very well at an image resolution of 500 ppi (197 pp/cm) and are reported in the following data.

APPARATUS & MATERIALS

Image Analysis System: All specimens were processed using Verity IA 2000 Mottle analysis software in a high speed personal computer. The computer was supplied with a large 256 MB memory that enhanced the processing of large images generated by an AGFA DuoScan graphic arts quality full color flat bed scanner. This particular scanner incorporates axially symmetric dual specimen illumination bulbs. The dual bulb construction eliminated image shadows caused by paper cockle, protruding fibers and heavy ink. Although an imaging resolution of 500 ppi was used on all these tests, the scanner camera was capable of optical resolutions up to 2000 ppi. In each analysis all bands were averaged together to produce an equally weighted 8 bit, 0-255 luminance value image. No mathematic or image optimization techniques were employed in the analysis. Enhancements were used, where noted, however, to generate some of the graphics presented in the following.

Presses: Two different Heidelberg offset presses were employed: At the Rochester Institute of Technology (RIT) in Rochester, NY, a six color sheet fed and at the Fox Valley Technical College (FVTC) in Appleton, WI, a four color sheet fed offset printing press.

Color Images, Color Bands, and Image Math

Inside a color scanner the color image is acquired with a digital camera usually having three rows of sensors, red, green, and blue (RGB), arranged in ranks one above the other. The individual RGB sensors are compacted horizontally to a density defined as the resolution expressed in North America as points per inch (ppi). When an image acquisition session is complete, the scanner driver software realigns the RGB picture point sensor rows to superimpose one upon the other and compute the color vector for each sensor point before the image is filed away, displayed on screen, or transferred to the image analysis software.

The color picture point sensors create three separate images, or color bands, that record, as a numeric value, the intensity of the light striking the sensor dedicated to that picture point location. In all image processing these three values are within the luminance vector so they can be reproduced and analyzed as a color image.

If necessary the SFDA mottle algorithm can take advantage of the RGB color separation by analyzing each band selectively or by combining the digital luminance values in each image mathematically. The separate RGB color luminance values range from 0 to 255, from dark to light respectively. These numeric luminance intensity values can be divided and multiplied together to create new images and provide a potential tool for the analysis of multicolor back-trap.

MEASUREMENT OF SINGLE COLOR, CYAN BACK-TRAP MOTTLE

Single color Set-up: The six color sheet fed offset press at RIT was used to test the ability of the SFDA algorithm to measure the effects of ink overprints, or back-trap, using heavy weight flat sheets, 18 point cover stock. The pattern shown in Fig 2 was used to print 100% cyan in three different areas of the pattern on unit 2. Two of these areas were then over-printed once more, one on unit 5 and the other on unit 6. The purpose was to determine if the SFDA algorithm could define differences in the degree of mottle induced by the multiple blanket exposures and the effect of blanket exposure on ink on ink. The print on unit 2 would experience 4 more blanket surfaces before exiting the press. The overprint at unit 5 would experience not only the effects of back-trap but one more blanket exposure. The overprint at unit 6 experienced no more blanket exposures.

Fig.3 shows an enhanced image of the printed pattern. The enhancement used an equalization tool that redistributes the image luminance values across the full 0 to 255 8 bit digital range to make visible the subtle differences measured by the SFDA algorithm.

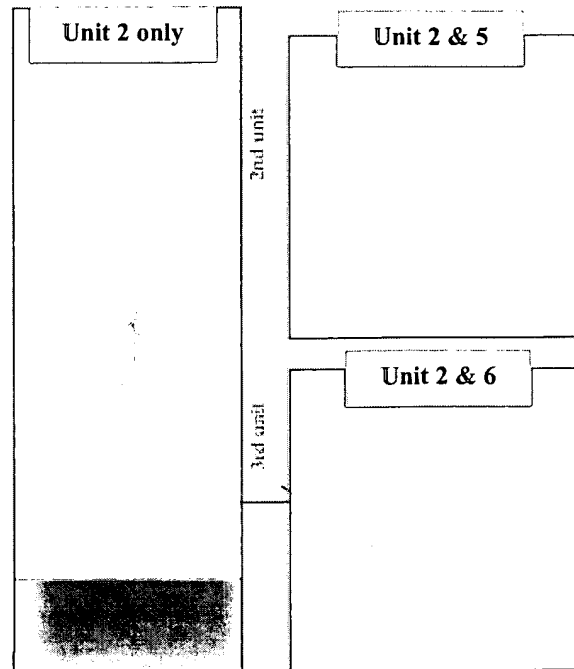


Figure 2 A scanned image of the pattern printed in cyan, magenta and black. Only the cyan is of interest and was printed in this order: starting top left, on unit 2 only; top right unit 2 then again on unit 5; lower right on unit 2 then again on unit 6.

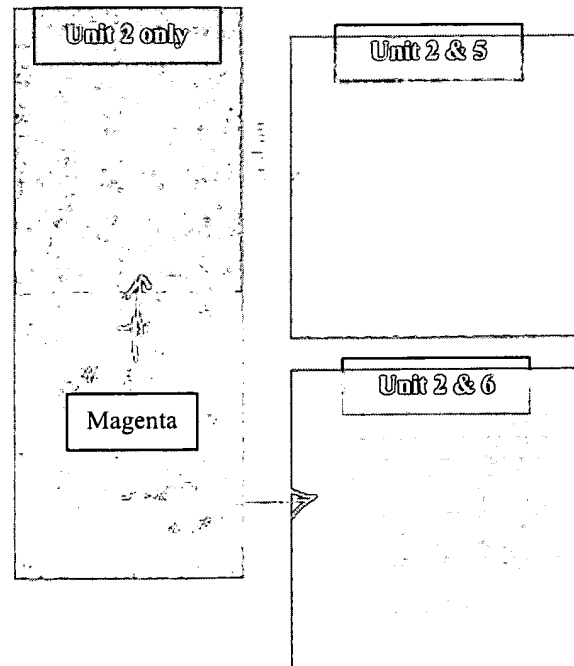


Figure 3 The printed pattern in Fig. 2 has been equalized across its luminance range to 0 to 255 in order to visually display the subtle contrasts measured by the SFDA algorithm.

SFDA Measurement: Fig. 4 shows the data from the SFDA measurement. Each area of the pattern was measured and data were reported independently.

Interpretation: As was anticipated the level of mottle declined proportional to the number of blanket exposures the wet ink received. In addition to the overall mottle measurement, the SFDA algorithm also extracts the horizontal and vertical components. What was unanticipated was the orientation phenomenon at unit 5 where the ink on ink was given an additional blanket exposure. In Fig. 4 the percentage difference between the horizontal and vertical components was scaled to 0.1 to fit the mottle scale.

MEASUREMENT OF BACK-TRAP MOTTLE ON DIFFERENT GRADES

The offset press at the Fox Valley Technical College was used to test the ability of the SFDA to measure back trap mottle in different grades of paper. An experiment was defined using different grades of paper from various suppliers to determine if the SFDA algorithm could distinguish between them and perhaps provide data to determine a grade scale. The pattern shown in Fig. 5 was digitally produced and directly etched on the plates. The ink lay down order was: Black, Cyan, Magenta, Yellow. The printed sheets were dried several days before testing.

Paper Grades Evaluated

These are the trade name descriptions provided by the suppliers. In some cases there was no metric basis weight provided.

- 1- Coated, Gloss, 60# Recycled Offset
- 2- Coated, Gloss, 100, Cover
- 3- Coated, Matte, 148 g/sq M, 100# Text
- 4- Uncoated, 104 g/sq M, 70# Text
- 5- Uncoated, 135g/sq M, 50# Cover

There were 5 sheets selected from the run and labeled A through E.

Single Sheet Test – Test Setup

Specimen 1A was selected from the group to evaluate and set the test parameters for the remaining specimens.

Interpretation of Data, Specimen 1A

These data are displayed in Fig. 6. Results show an orientated mottle pattern not apparent to the naked eye.

The chart in Fig 6 graphically illustrates the orientation phenomenon trending from the left towards the right side of the pattern. There is a subtle streak running down the right edge of the pattern that is visually apparent when the image equalization algorithm is applied to each area. The measurement indicated this streak and numerically evaluates it.

The blue, a back-trap composed of the cyan and the magenta inks, and the yellow primary, each of which are printed immediately above the CMYK, all demonstrate the same streaking tendency.

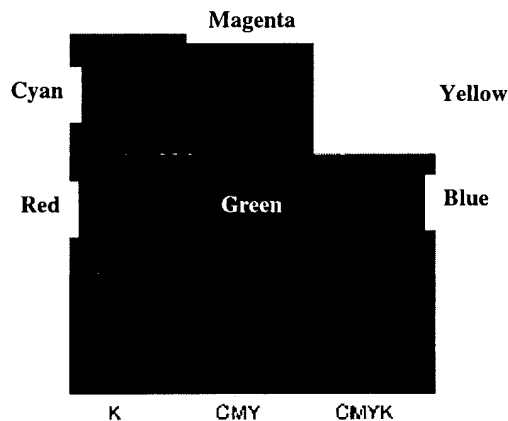
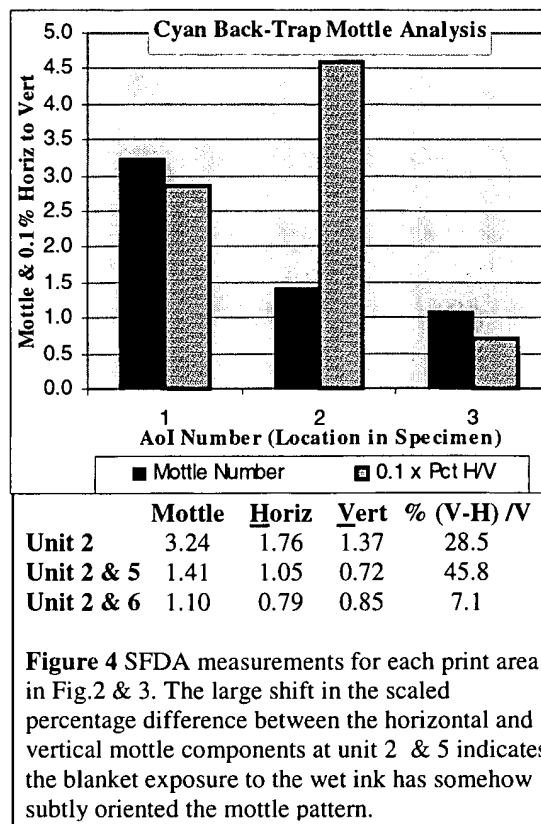


Figure 5 The multi-colored pattern used in the multi-grade tests is shown here in monochrome. Each of these printed squares is 25.4 mm square. The unit color order on the press was KCMY.

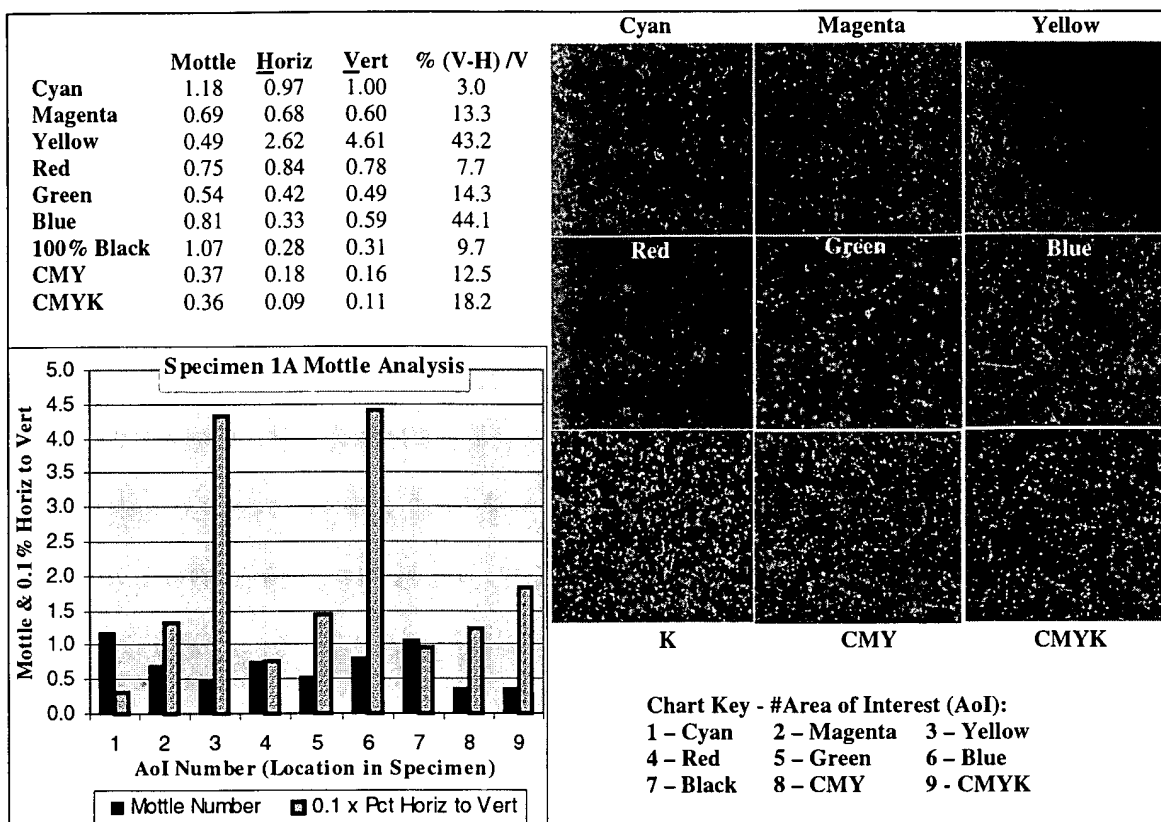


Figure 6 Texture mottle with a 5 pp square target on specimen 1A. The image of each square as shown in Fig 5 has been equalized in gray scale to show the mottle more clearly in monochrome half-tone print. Of special note is the right to left variations in the Yellow - Blue - CMYK column. There is an apparent streak either in the paper or the press that is causing this phenomenon. As shown in the chart, although there was less overall mottle in these areas, the measurement picked up on this left to right aberration.

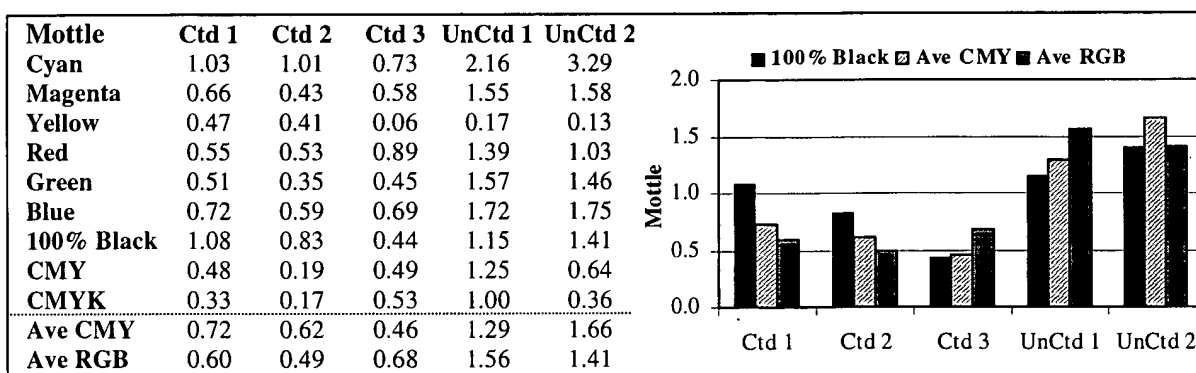


Figure 7 SFDA mottle test using a 5 pp square target. These data are the average of five specimens from each grade, each printed with the pattern shown in Fig 5. To generate the chart, data were grouped and averaged as CMY and RGB, and 100% Black is as reported. There is a clear distinction between the coated and uncoated grades. Note in the data, the YELLOW does not follow the trend of the Cyan and Magenta, it has a lower mottle level in the uncoated grades with the matte finish coated grade exhibiting the least mottle.

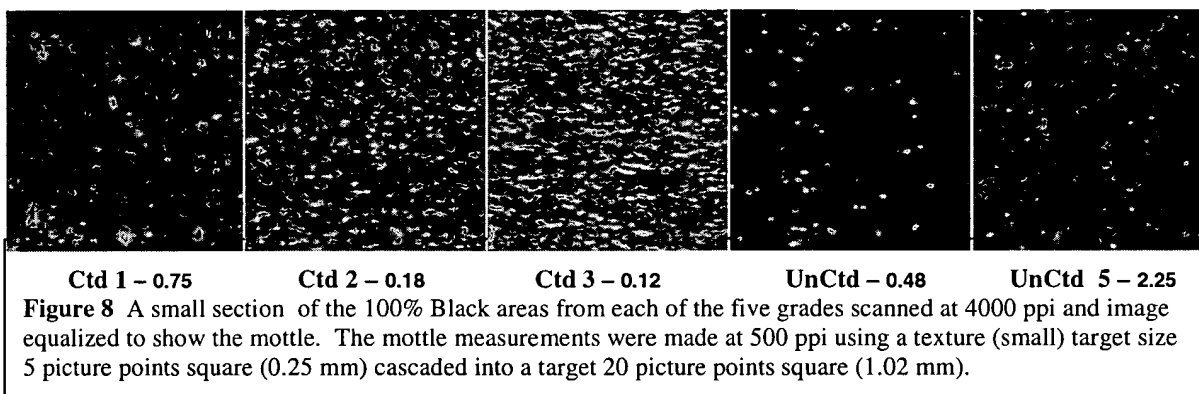
Multiple Grades Test

About 100 sheets of each grade were printed with the pattern shown in Fig. 5. From each grade sample 5 sheets were selected at random and tested using the SFDA mottle algorithm and a target size of 5pp wide. Data from these 5 specimens from each grade were averaged to create the table shown in Fig 7.

Interpretation of Data, Multi-Grade Tests

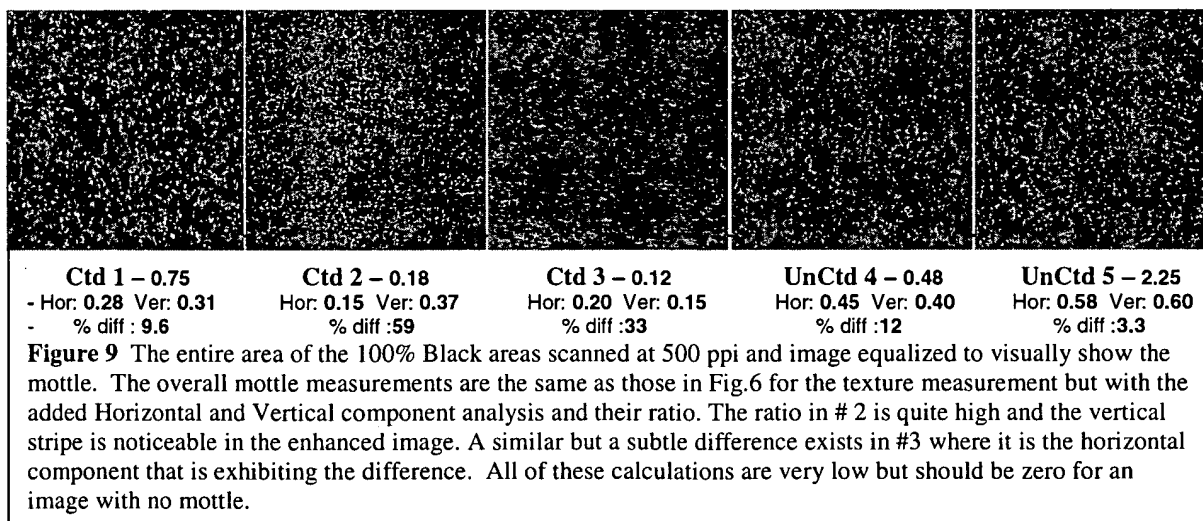
There was a plethora of data produced very quickly from the tests of the nine (9) areas on each sheet. Prior to generating the chart in Fig 7, these data were further grouped by averaging together the cyan, magenta and yellow primaries, and then the red, green and blue back-trap, within each grade. These data were then charted along with the 100% black. The individual sheets showed variations with in the specimen group but were not significant enough to warrant charting the individual specimen results.

Using any criteria except yellow, these results clearly demonstrate the ability of the algorithm to distinguish between the coated and uncoated sheets and to grade them. The yellow ink behaves differently and in fact may have a right to left streak that persists through the entire test series. Hints of this phenomenon are provided in the data in Fig 6. The detail data, not shown here, indicate there may be an erratic appearance of the streak.



Streaking & Spatial Distribution

The data presented in Fig 6 show the measurement of streaking. Fig. 9 shows enhanced views of the 100% Black areas with the horizontal to vertical percent differences. It is visually evident in these equalized views that the mottle measurement is representative of the mottle present in the printed image.



SPATIAL DISTRIBUTION

Mottle may be recognized by the human eye on several different levels at the same time. Up to this point in the work only the smallest target has been used to measure mottle which, at a resolution of 500 ppi, this target is 5 pp wide or 0.250mm, making it visible to the unassisted eye. This small target is measuring the texture of the image by analyzing data acquired from the underlying sub-visible pixels.

By grouping these small targets into larger targets the spatial distribution of the underlying visible image texture can be measured also. To illustrate its use, the 100% black area on one sheet of each specimen set was equalized and shown in Fig 8 & 9. These same areas were measured for all five sheets in the sets and the data averaged to produce the chart shown in Fig. 10. Uncoated 2 demonstrates a definite variation in the texture distribution at the 1mm level. This effect can be visualized in Fig 8 as blotchiness. It also shows up in Coated 2 but to a lesser extent primarily because of the uniform right to left streaking phenomenon also present.

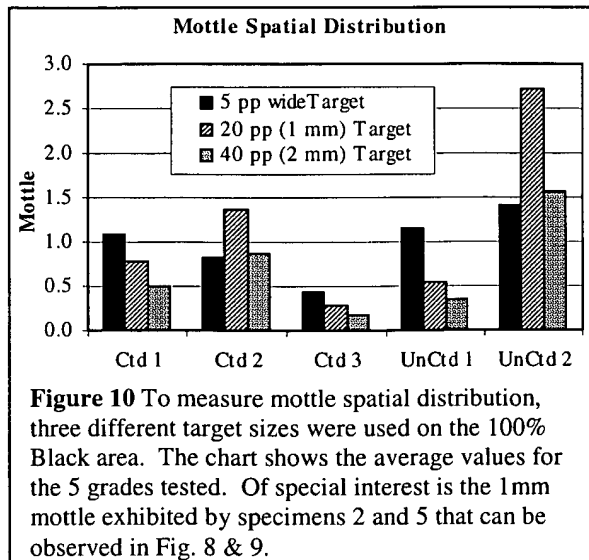


Figure 10 To measure mottle spatial distribution, three different target sizes were used on the 100% Black area. The chart shows the average values for the 5 grades tested. Of special interest is the 1mm mottle exhibited by specimens 2 and 5 that can be observed in Fig. 8 & 9.

For complete homogeneity the target measurements should be inversely proportional to their size as demonstrated in specimen sets Coated 1 & 3 and Uncoated 1.

CONCLUSIONS

Stochastic frequency distribution analysis yields a dimensionless number derived from the underlying digital image pixel luminance value statistical variance. It provides an objective means to evaluate the influence of press, ink, and paper upon the resulting printed image. In particular, it provides a method to evaluate the effect of ink formulation and properties, blanket performance, effects of multiple applications of wet ink, and the response of the paper to press conditions and the distribution of pits and voids in the sheet surface.

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